K110900

SUMMARY OF SAFETY AND EFFECTIVENESS

JUN 24 2011

1 GENERAL INFORMATION

1.1 Submitter and Owner of the 510(k)

BloXR Corporation
2116 Lakeline Drive
Salt Lake City, Utah 84109

1.2 Official Correspondent

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1.3 Date of Preparation

March 28, 2011

2 NAME OF THE DEVICE

2.1 Trade/Proprietary Name

Thyroid Collar (Disposable)

2.2 Common/Usual Name

Thyroid Collar

2.3 Classification Information

Classification Name: Personnel Protective Shield

Classification Regulation: 21 CFR § 892.6500

Class: I

Product Code: KPY

Panel: Radiology

3 PREDICATE DEVICES

The predicate devices are as follows:

1) the Cost Cruncher Thyroid Collar, a class I device; and,
2) the Starlite Thyroid Collar, a class I device.

The predicate devices are Personnel Protective Shields (21 CFR 892.6500) and have been classified as Class I medical devices.

4 DESCRIPTION OF THE DEVICE

The Disposable Thyroid Collar is a radiation protective shield for the thyroid intended to be used in various medical procedures where X-ray radiation is used. It is a non-sterile device, designed for single use. The device is constructed with environmentally friendly radiation attenuating materials, which do not contain lead or heavy metals. The radiation attenuating material is encased in a medical grade polypropylene (PP) non-woven drape material. The device is available in three sizes, small, medium, and large.

The device blocks radiation in a similar manner to lead – via absorption of the photon energy from ionizing radiation. This photon energy is dissipated as phonon energy within the atomic lattice structure of the radiation attenuating material, in a manner identical to lead.

5 INDICATIONS FOR USE AND INTENDED USE

The BloXR Disposable Thyroid Collar has the following indications for use:

> *The Disposable Thyroid Collar is indicated for use as a radiation shield against scatter radiation. It is intended to be placed around the neck of the user who remains outside of the primary radiation beam.*

This is the same intended use as the predicate devices.

The Disposable Thyroid Collar and the predicate devices all have the same intended use – namely, to attenuate scatter radiation to protect the user. The BloXR Disposable Thyroid Collar and the predicate devices all share the same primary function; that is, to physically block ionizing radiation. All the devices provide a physical barrier to attenuate the ionizing radiation. Each device is worn by the users around their necks to provide protection from scatter radiation. Each device is available without a prescription and is intended to be used in a health care facility where ionizing radiation is in use.

6 TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICES

The BloXR Disposable Thyroid Collar has the same design and shares many similar design characteristics to the predicate devices, the Cost Cruncher and the Starlite Thyroid Collars. All of the devices are available in a similar configuration to be worn easily around the neck; all of the devices include a mechanism to fasten the device around the neck.

All of the devices operate using the same fundamental scientific technology – they absorb the photon energy from ionizing radiation to provide protection. This photon energy is dissipated as phonon energy within the atomic lattice structure of the particulate absorber material. Each device, however, uses different materials to absorb the photon energy. The BloXR Disposable Thyroid Collar uses a proprietary material to absorb photon energy, which is encased in a polypropylene fabric. One of the predicate devices, the Cost Cruncher, uses a lead vinyl formula to absorb photon energy, whereas the Starlite uses a heavy-metal (lead-free) vinyl composite (details unspecified). Although they use different materials, each device is intended to provide a 0.5 mm lead equivalent protection. The BloXR Disposable Thyroid Collar is disposable whereas the predicate devices are reusable. The new device is provided disposable for hygienic and user preferences.

7 PERFORMANCE TESTING

The performance data presented in this 510(k) application demonstrate the BloXR Disposable Thyroid Collar is substantially equivalent to the predicate devices. The BloXR Disposable Thyroid Collar is made from materials with a known and established safe history of use in medical devices, which are suitable and safe for skin contact.

BloXR conducted two laboratory studies, one at an independent laboratory and the other in-house, to evaluate and compare the radiation shielding properties of the device materials of the Disposable Thyroid Collar to the two predicate devices and to a 0.5 millimeter (mm) lead sheet, as a control. The devices were tested at X-ray radiation levels of 60, 90, 100 and 120 KVp using the methodology described in ASTM F 2547-06 "Standard Method for Determining Attenuation Properties in a Primary X-ray Beam of Materials Used to Protect against Radiation Generated during the Use of X-ray Equipment." The attenuation level provided by BloXR materials was similar to the predicate devices and the 0.5 mm lead sheet, demonstrating substantial equivalence.

8 CONCLUSIONS

This 510(k) submission demonstrates that the Disposable Thyroid Collar is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUN 24 2011

BloXR Corporation
c/o Rai Chowdhary
Vice President of Operations and Engineering
2116 Lakeline Drive
SALT LAKE CITY UT 84109

Re: K110900
Trade Name: Disposable Thyroid Collar
Regulation Number: 21 CFR 892.6500
Regulation Name: Personnel protective shield
Regulatory Class: I
Product Code: KPY
Dated: March 28, 2011
Received: March 31, 2011

Dear Mr Chowdhary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 4 – Indications for Use

Indications for Use Form (Text Version)

Indications for Use

510(k) Number (if known): K110900

Device Name: Disposable Thyroid Collar

Indications for Use:

The Disposable Thyroid Collar is intended for use as a radiation shield against scatter radiation. It is intended to be placed around the neck of the user who remains outside of the primary radiation beam.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __Yes_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Mary S Patel DRAD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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